

§ 522.1451

fourth-stage larvae), *Nematodirus helvetianus* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; mites: *Psoroptes ovis* (*Psoroptes communis* var. *bovis*); lice: *Linognathus vituli* and *Solenopotes capillatus*; for protection of cattle from reinfection with *D. viviparus* and *O. radiatum* for 42 days after treatment, with *H. placei* for 35 days after treatment, and with *O. ostertagi* and *T. axei* for 14 days after treatment.

(3) *Limitations*. Do not slaughter cattle within 21 days of treatment. Because a withholding time for milk has not been established, do not use in female dairy cattle 20 months of age and older. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

[70 FR 36337, June 23, 2005, as amended at 71 FR 7414, Feb. 13, 2006; 76 FR 48714, Aug. 9, 2011]

§ 522.1451 Moxidectin microspheres for injection.

(a) *Specifications*. The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use; dogs*—(1) *Amount*. 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) *Indications for use*. For prevention of heartworm disease caused by *Dirofilaria immitis*; for treatment of existing larval and adult hookworm (*Ancylostoma caninum*) and *Uncinaria stenocephala* infections.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 35756, July 9, 2001, as amended at 67 FR 57944, Sept. 13, 2002; 79 FR 16191, Mar. 25, 2014]

21 CFR Ch. I (4–1–14 Edition)

§ 522.1452 Nalorphine.

(a) *Specifications*. Each milliliter of solution contains 5 milligrams of nalorphine hydrochloride.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. One milligram per 5 pounds; intravenously, intramuscularly, or subcutaneously.

(2) *Indications for use*. Respiratory and circulatory depression in dogs resulting from overdosage of, or unusual sensitivity to, morphine and certain other narcotics. Not for depression due to any other cause.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 6707, Feb. 2, 1979, as amended at 47 FR 36418, Aug. 20, 1982; 62 FR 63271, Nov. 28, 1997; 79 FR 16191, Mar. 25, 2014]

§ 522.1465 Naltrexone.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams of naltrexone hydrochloride.

(b) *Sponsor*. See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use in elk and moose*—

(1) *Amount*. 100 milligrams of naltrexone hydrochloride for each milligram of carfentanil citrate administered. One-quarter of the dose should be administered intravenously and three-quarters of the dose should be administered subcutaneously.

(2) *Indications for use*. As an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*).

(3) *Limitations*. Do not use in domestic food-producing animals. Do not use in free-ranging animals for 45 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 5320, Feb. 5, 1997, as amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1468 Naproxen for injection.

(a) *Specifications*. The drug is a lyophilized powder which is reconstituted with sterile water for injection to form a 10 percent sterile aqueous solution (100 milligrams per milliliter).

(b) *Sponsor*. See 054771 in § 510.600(c) of this chapter.